

**1.0 510(k) SUMMARY****AUG - 7 1996****(1) Submitter's Information**

UNIVAC Inc.  
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Garden City, New York 11530  
(516) 294-1000 (tel)  
(516) 739-3343 (fax)

**(2) Device Name**

Proprietary Name:	UNIVAC Nonreusable Locking Syringe
Common or Usual Names:	Piston; Hypodermic Needle
Classification Names:	Piston Syringe 21 C.F.R. 880.5680 Class II  Hypodermic single lumen needle 21 C.F.R. 880.5570 Class II

**(3) Predicate Device:**

K 943679, UNIVAC Nonreusable Locking Syringe with non-aspirating  
plunger

**(4) Description of Device:**

The UNIVAC Nonreusable Syringe with Coupling Assembly provides a single use function. This assembly, inserted between the syringe plunger and the syringe rubber stopper, will decouple the plunger from the stopper (and disable the syringe) after injecting one dosage of serum. The assembly materials will be fabricated from the same polypropylene as the syringe.

**(5) Statement of Intended Use**

The UNIVAC Nonreusable Locking Syringe with Coupling Assembly can be used by health care professionals, diabetics and other persons for injection of insulin, tuberculin, immunization serum, and other injectible medications.

**(6) Statement of Technological Characteristics**

The UNIVAC Nonreusable Locking Syringe with Coupling Assembly has no significant change in design, except for the stainless steel locking clip of the predicate. Otherwise, it has the same material, chemical composition, energy source, or other technological characteristics compared to the predicate device listed in paragraph (3).